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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/866,060	05/25/2001	James W. Whittaker	HME/8134.003	4178

29085 7590 08/22/2003

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EXAMINER

PAK, YONG D

ART UNIT	PAPER NUMBER
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1652

22

DATE MAILED: 08/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/866,060

Applicant(s)

WHITTAKER ET AL.

Examiner

Yong D Pak

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 18, 20 and 21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 18, 20 and 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

The amendment filed on June 5, 2003, canceling claims 6-8, 10-11, 16-17 and 19 and amending claims 1, 18 and 20 and entering claims 21-22, has been entered.

The finality of the rejection of the Office Action of April 22, 2003 is withdrawn.

Claims 1-5, 18, and 20-21 are pending.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-5 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Golightly et al. in view of Zamost et al.

Golightly et al. (U.S. Patent 6,277,612) teach DNA encoding a galactose oxidase linked to an *Aspergillus niger gla* signal peptide and an inducible promoter that regulates transcription of the sequence encoding the construct (claims 13 and 16, Columns 10-13 and Column 11). Golightly et al. also teach vectors comprising said DNA construct (claims 14-15 and 17-18 and Columns 13-17). Further, Golightly et al. also teach a method of producing the galactose oxidase using the vectors comprising the construct (claim 19 and Columns 10-17).

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The difference between the reference of Golightly et al. and the instant invention is that the reference of Golightly et al. does not teach a DNA encoding the galactose oxidase linked to a methanol-inducible promoter and a galactose oxidase that is inactive.

Zamost et al. a method for producing a target polypeptide in a *Pichia* host cell wherein the polypeptide is under the control of a methanol-inducible promoter and a vector comprising the target polypeptide and the methanol-inducible promoter (claims 1 and 11 and Columns 3-10). Zamost et al. teach a method wherein the transformed cell is cultured at 30 C and induced at a lower temperature (Column 26, lines 15-33). Zamost et al. teach that methanol is a volatile carbon source and it is readily lost on prolonged incubation (Column 24, lines 43-49). It would have been obvious to one of ordinary skill in the art to optimize the induction process by lowering the temperature to room temperature (McAleer et al., page 130, 2nd column).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to use a methanol-inducible promoter to produce the protein in a *Pichia* host. The motivation of using a methanol-inducible promoter and a *Pichia* host is to effectively produce recombinant proteins. One of ordinary skill in the art would have had a reasonable expectation of success since *Pichia* hosts are routinely used in the art for the production of recombinant proteins and since methanol-inducible promoters have been used successfully in inducing proteins.

Claims 1-2 and 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Golightly et al. in view of Zamost et al. as applied to claims 1, 3-5 and 18 above, and further in view of Montague-Smith et al.

Golightly et al. and Zamonst et al. in combination teach a galactose oxidase expressed in an inactive form, as discussed above. Zamost et al. also teach that methylotrophic yeasts such as a *Pichia*, are attractive candidates for use in recombinant protein production systems (Column 1, lines 19-65). One of ordinary skill in the art would recognize that proteins are usually inactive due to the presence of methanol in the culture medium.

The difference between the combined teaching of Golightly et al. and Zamost et al. is that the references do not teach activating the inactive protein with an oxidant.

Montague-Smith et al. teach that galactose oxidases can be activated by treatment with one-electro oxidants, such as ferricyanides (page 354, 1st and 2nd paragraph). Once the enzyme is activated by the oxidant, one of ordinary skill in the art would recognize that the enzyme would oxidize substrates and substrate like contaminants.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to activate the inactive galactose oxidase with the oxidant of Montague-Smith et al. The motivation of using the oxidant of Montague-Smith et al. is to activate the inactive protein. One of ordinary skill in the art would have had a reasonable expectation of success since Montague-Smith et al. successfully activated the protein.

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No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 703-308-9363. The examiner can normally be reached on 8:00 A.M. to 4:30 P.M weekdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Yong Pak
Patent Examiner



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